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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,391	11/14/2000	Jurgen Bongs	02481.1716	3417

22852 7590 08/25/2003

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/25/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/700,391

Applicant(s)

BONGS ET AL.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-23 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/5/03 has been entered.

Claims 12-23 are being examined on the merits. Claim 11 is withdrawn from consideration as directed to a non-elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is incomplete and vague, indefinite and confusing in the recitation "extracting said biomolecules from the group consisting of..." without an indication of the source and nature of the biomolecules. There is no clear relationship between the bonded enzymes and the biomolecules. Are the "biomolecules" extracted from peptides, proteins, oligosaccharides and polysaccharides? How? There is no clear indication as to the nature of the extracted product or how it is extracted with unidentified and unrelated enzymes.

Claim 13 is incomplete and vague and indefinite in lacking a definition of the extractant, the substrate extracted and the extracted product as well as the process steps used in the extraction. The claim fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For example, the nature of "analogs" of insulin and of "corresponding precursors" at a least of insulin analogs is uncertain. There is no clear indication of the extracted product or how it is extracted from insulins or their analogs. There is no clear nexus between the immobilized enzymes, the extraction process and the production of biomolecules. The nature of "biomolecules" obtained is not defined with any particularity.

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Claims 20 and 21 fail to find clear antecedent basis in claim 13 for "the reaction", in the absence of reaction steps.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

With respect to "analog", there is no definition of this terminology in the as-filed specification, but only a discussion of how "analog" may be "derived" (Specification, page 3, paragraph 5). Therefore, the metes and bounds of this term are unclear.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Perry.

The claims are directed to the enzymatic extraction of biomolecules using a polymeric support material which has no pores.

The reference teaches the enzymatic extraction of an antigen, which is clearly a biomolecule using the polymeric support material which has no pores Eupergit<sup>R</sup> C1Z having an enzyme bonded thereto. It is noted that "extraction" is defined as "pulling out" or "separating". See, e.g., Example 1.

Claim 12, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Graessel *et al.*.

The claims are directed to the enzymatic extraction of biomolecules using a polymeric support material which has no pores.

The reference teaches the enzymatic extraction of an antigen, which is clearly a biomolecule using the polymeric support material which has no pores Eupergit<sup>R</sup> C1Z having an enzyme bonded thereto. It is noted that "extraction" is defined as "pulling out" or "separating". See, e.g., page 72.

While there may be allowable subject matter in the present application, this material has not been presented in a manner that would permit reaching that conclusion.

The following aspects/features of the claimed invention if properly claimed would be given favorable consideration. Claims directed to a process of extraction of insulin using trypsin immobilized on the specific support Eupergit<sup>R</sup> C1Z from preproinsulin.


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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

  
Irene Marx  
Primary Examiner  
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